

## **REMARKS**

Claims 21-22 are pending in the application. No claim is allowed.

Claims 21-22 are rejected under 35 USC 103(a) as allegedly being unpatentable over Brekke, et al. (WO 94/09722, "Brekke"). Applicant respectfully traverses the rejection and request that it be reconsidered and withdrawn.

The Examiner relies upon Brekke to show a composition for treating bone such as abnormal bone at a tissue site of desired bone growth and that hyaluronic acid (HA) is a carrier for osteoinductive/osteogenic agents by chemical binding, as well as by mechanical entrapment. The examiner further relies on Brekke to show that an osteoinductive/osteogenic substance or growth factor can be injected as a solution. The examiner concludes that these alleged teachings would suggest to one of ordinary skill in the art that HA as a carrier can be combined with a growth factor and injected or applied as a solution at the tissue site of desired bone growth to treat bone such as an abnormal bone.

Applicant disagrees that Brekke would suggest this to one of ordinary skill in the art. It is submitted that upon a careful reading of Brekke, structural competence is required, that is, a gross structure to provide a mechanical support and structural surface for the dynamic biological processes for genesis, growth and development of new non-calcified and calcified connective tissue. This function is served by the biologically acceptable, biodegradable solid polymer (such as polylactic acid) arranged as a one piece porous solid body with enclosed randomly sized, randomly positioned and randomly shaped interconnecting voids, each void communicating with all of the others, and communicating with substantially the entire exterior of the body. Note that Brekke, on page 20, lines 11-13, already has in his possession a gel of HA and a solution of osteoinductive/osteogenic agent (page 19, line 30 to page 20, line 4). But Brekke does not mix them together and use them on the bone tissue site. Brekke does not even mix HA and the agent together as a two-component liquid system. The suggestion to one of ordinary skill in the art, it is submitted, is that it would be useless to do that because neither substance would provide support for the other for retention at the bone wound site. There would ostensibly be no way to sufficiently support the agent and retain it at the site as a liquid or gel for a period sufficient for the agent to act. One of ordinary skill in the art would recognize that if one applies a liquid or gel to a wound, for example, the liquid would run off in a matter of seconds and a gel might remain at the site a matter of minutes. There is simply no

support to keep it at the site. This common sense deduction is reinforced by Brekke. Brekke lyophilizes the HA gel within the porous solid polylactate body (page 20, line 11-12), and injects the agent solution into the polylactate body (page 20, lines 14-17). Then there is support for the agent and it can be placed on the desired site of bone growth as shown in Fig. 7 as a solid block. The block is press fit into a bone cavity which thus locks the device at the site so it can be retained there for the requisite healing period. See page 25, lines 4-9.

For these reasons, it should be clear that Brekke teaches away from combining HA and the agent and applying that combination as is directly upon a desired site of bone growth without a further means of solid support.

In contrast, according to the present invention, the recited components are injected as a liquid together onto the tissue site of desired bone growth. See p. 4, lines 8-17; p. 3, lines 18-25; p. 5, lines 21-23; p. 11, lines 2-11 and 18-21; p. 13, lines 18-21; and p. 19, lines 14-19.

It is submitted that the teaching of the methods in Brekke to one of ordinary skill in the art would be that in order to induce the growth of bone, one needs the solid macrostructure, and possibly also the solid microstructure, of the device in Brekke. This is a teaching away from the presently claimed invention.

For the foregoing reasons it is submitted that the claims are unobvious under 35 103(a) over Brekke. Entry of this amendment and withdrawal of the rejection are respectfully requested.

Applicant hereby petitions for any extension of time that may be required to maintain the pendency of this case, and any required fee for such extension or any further fee required in connection with the filing of this amendment is to be charged to Deposit Account No. 504480 (Order No. DEYP003D1C1).

Respectfully submitted,  
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